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16 IN THE UNITED STATES DISTRICT COURT  
17 IN AND FOR THE SOUTHERN DISTRICT OF CALIFORNIA  
18 SAN DIEGO DIVISION

18 ISIS PHARMACEUTICALS, INC., a  
19 Delaware Corporation,

20 Plaintiff,

21 v.

22 SANTARIS PHARMA A/S CORP., a  
23 Delaware corporation, and SANTARIS  
24 PHARMA A/S, a Danish Corporation,

25 Defendants.

26 AND RELATED COUNTERCLAIMS

NO. 11CV2214 GPC (KSC)

**RESPONSE TO DEFENDANTS'  
OBJECTIONS TO MAGISTRATE JUDGE  
CRAWFORD'S JULY 5, 2013 ORDER  
DETERMINING DISPUTE RE: DR.  
DEAN**

27 ***PUBLIC VERSION***

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1     **I. INTRODUCTION**

2           The testimony of an expert with experience in antisense drug discovery and  
3 development is critical to Plaintiff Isis Pharmaceutical, Inc.’s (“Isis”) response to  
4 Defendants Santaris Pharma A/S and Santaris Pharma Corp.’s (collectively,  
5 “Santaris”) defense that their activities are all exempted from infringement by the  
6 safe harbor set forth in 35 U.S.C. § 271(e)(1) (the “Safe Harbor”). Isis has retained  
7 Dr. Nicholas Dean for that purpose and Judge Crawford entered a July 5, 2013  
8 order (Dkt. No. 172) (the “Order”) granting Dr. Dean access to information Santaris  
9 has designated as Confidential or Confidential Attorneys Eyes Only in light of the  
10 substantial prejudice to Isis absent such relief. Santaris’s objections to the Order  
11 should be rejected.

12           Santaris’s objections contain eleven pages of argument. Over half of that  
13 argument is devoted to the contention that the Order “vitiates Santaris’s rights  
14 under the protective order to make reasonable objections to disclosure of its  
15 Confidential Information.” Nowhere in this fulsome argument does Santaris  
16 address a simple point: it has not quoted the entirety of Paragraph 8 of the  
17 Amended Protective Order upon which it relies to make this argument. Moreover,  
18 it does not disclose to the Court that it cherry-picked the portions of Paragraph 8  
19 that suit its “argument” while omitting a key provision in Paragraph 8 that it cited  
20 below before Judge Crawford.

21           Santaris’s “quotation” of Paragraph 8 of the Amended Protective Order at  
22 page 3 of its objections conveniently deleted, among other things, the following  
23 sentence: “The right of any Independent Expert to receive any Confidential  
24 Information will be subject to the advance approval of such expert by the producing  
25 party *or as approved by the Court.*” (Dkt. 144, ¶ 8.) (emphasis added). The  
26 original Protective Order likewise stated: “The right of any independent expert to  
27 receive any Confidential Information will be subject to the advance approval of  
28 such expert by the producing party or as approved by the Court.” (Dkt. No. 59, ¶8.)

1 Thus, each party knew at all times that the Court could enter an order granting an  
2 opposing expert access to its Confidential Information. In fact, they stipulated to  
3 this in the original Protective Order.

4 Santaris's decision to omit in its objections to this Court any reference to the  
5 "Court approval" language in the Protective Orders was deliberate, as shown by the  
6 fact that it quoted this sentence before Judge Crawford repeatedly and did not,  
7 unlike now before this Court, omit this sentence. (*See* Dkt. 113, at 9, 33.) Isis  
8 likewise quoted this same sentence before Judge Crawford. (*Id.*, p. 14.)

9 Santaris's remaining objections are equally baseless, and Isis asks that the  
10 Court expeditiously reject Santaris's objections. The proceedings on this issue  
11 before Judge Crawford were extensive. The parties spent over eight months first  
12 meeting and conferring and then presenting their dispute regarding Dr. Dean to  
13 Judge Crawford. This included the filing of two separate joint motions totaling  
14 over 95 pages, the submission of 12 declarations, over 88 exhibits, a lengthy  
15 hearing before Judge Crawford in May 2013, and two orders culminating in the  
16 Order on July 5, 2013. On this record, Santaris's objections do not come close to  
17 showing that Judge Crawford's findings of fact were clearly erroneous or that her  
18 legal conclusions were contrary to law.

## 19 **II. SUMMARY OF RELEVANT FACTS**

### 20 **A. THE ANTISENSE FIELD**

21 The antisense drug discovery field is a small, close-knit field. (Dkt. No. 113-  
22 16 ¶ 19.) Founded in 1984, Isis is among the earliest and most important  
23 innovators in the antisense drug discovery field. (*Id.*) Only two antisense drug  
24 products have ever been approved by the Food and Drug Administration ("FDA").  
25 (Dkt. No. 113-1 ¶¶ 18, 20.) Both were discovered by Isis. (*Id.*) As a result, many  
26 of the consultants or scientists with experience in antisense drug discovery and  
27 development have current or former affiliations with Isis. (Dkt. No. 113-16 ¶ 19.)  
28

1 Many consultants or scientists who provide services to companies in the antisense  
2 field provide services to multiple, often competing, companies in the industry. (*Id.*)

3 **B. EXPERTS**

4 **1. Nicholas M. Dean, Ph.D.**

5 Dr. Dean is one of the only individuals who both is not currently an  
6 employee of an antisense drug discovery company and has extensive experience in  
7 antisense drug discovery and development. (Dkt. No. 113-1 ¶ 20.) Dr. Dean has a  
8 Ph.D. in Pharmacology, and has authored over ninety peer-reviewed articles,  
9 reviews and book chapters related to antisense technology. (Dkt. No. 113-16 ¶ 9.)  
10 He is an inventor on more than 40 issued U.S. Patents related to antisense  
11 technology, and has secured over \$500,000 in funding for antisense research from  
12 public sources, including from the National Institutes of Health, UC BioStar, and  
13 from the California Breast Cancer Program. (*Id.* ¶ 9.)

14 Dr. Dean's drug discovery and development career spans over 30 years, with  
15 14 of those years spent as an employee of Isis. (Dkt. No. 113-16 ¶¶ 8-10; Dkt. No.  
16 113-17 ¶ 2.) The remaining 16 years were at other companies. (*Id.*) Dr. Dean left  
17 Isis in January 2006, when he was laid off by Isis as part of a reduction in force.  
18 (*Id.*) Dr. Dean does not currently have a business relationship with Isis or any of its  
19 employees, nor is he a competitive decision-maker for Isis. (*Id.*; Dkt. No. 113-17 ¶  
20 3.)<sup>1</sup>

21 After leaving Isis, Dr. Dean founded Excaliard Pharmaceuticals, Inc.  
22 ("Excaliard"), a company devoted to the development of antisense therapeutics  
23 targeted to skin scarring and fibrosis. Dr. Dean served as Excaliard's Founder,  
24 Chief Scientific Officer, and a Member of Excaliard's Board. (Dkt. No. 113-16 ¶  
25 3.) Dr. Dean's employment with Excaliard terminated in February 2012, shortly  
26 after it was acquired by Pfizer, Inc. ("Pfizer"). (*Id.*) Dr. Dean consulted for Pfizer

27 \_\_\_\_\_  
28 <sup>1</sup> Dr. Dean occasionally socializes with one Isis employee, Frank C. Bennett, Ph.D,  
but does not otherwise socialize with Isis. (Dkt. No. 149-1, Ex. 17.)

1 on transition matters for approximately six months after the end of his employment.  
2 (*Id.* ¶ 4.) Dr. Dean has not entered into any subsequent consulting agreements with  
3 Pfizer, nor has he performed any consulting services for Pfizer since his consulting  
4 agreement expired in August 2012. (*Id.*) Dr. Dean, whose consulting activities are  
5 discussed in more detail, also serves as a consultant to several different companies.  
6 (*Id.* ¶ 3.)

7 Dr. Dean has been retained by Isis's counsel to provide expert opinions and  
8 information regarding the antisense drug discovery process as it relates generally to  
9 the subject matter of the claims of the patents at issue in this case. (Dkt. No. 113-  
10 16 ¶ 2.) Dr. Dean previously submitted a declaration on these topics in connection  
11 with Isis's opposition to Santaris's prior unsuccessful MSJ. (*Id.*; Dkt. No. 23.)

12 Dr. Dean has signed Exhibit A to the Protective Order entered in the case,  
13 agreeing to comply with and be bound by the terms of the Protective Order. (*Id.*  
14 ¶ 13, Ex. 2.) Dr. Dean has also specifically agreed that he would be bound by a  
15 patent prosecution bar. (*Id.*) In addition to the Protective Order, Dr. Dean has also  
16 agreed that in the event that he encounters documents or information produced by  
17 Santaris relating to non-public Santaris targets that are under consideration by any  
18 of his clients, he will immediately cease review of such documents pending Santaris  
19 approval or further order of the Court and will discontinue consulting with respect  
20 to such targets. (*Id.* ¶ 20; Dkt. No. 113-¶ 5.)

21 Dr. Dean has a long track record of protecting proprietary and confidential  
22 information, spanning over 30 years of drug discovery and development work, and  
23 has never been accused of violating any confidentiality obligation. (Dkt. No. 113-  
24 16 ¶ 12.) Apart from the fact that any violation of the Protective Order would  
25 potentially subject Dr. Dean to serious penalty, any such violation would ruin his  
26 reputation in the closely-knit antisense field, in which the ability to preserve  
27 confidential information is required to remain a member in good standing of the  
28 field. (*Id.* ¶ 13.)

1 Turning to Isis and Dr. Dean, Santaris's continued reliance on the former  
2 relationship between Isis and Dr. Dean only serves to highlight that its objections  
3 lack merit. *See Ares-Serono, Inc. v. Organon Int'l B. V.*, 153 F.R.D. 4, 6 (D. Mass.  
4 1993) (finding expert independent where "[s]ignificantly, Carter no longer occupies  
5 a position at Serono. In the past...she was actively involved in decisions connected  
6 with securing regulatory approval for fertility drugs, according to defendants'  
7 representation. The extent of Carter's employment and association with Serono in  
8 the past is therefore considerable. The extent of her present involvement, however,  
9 is minimal.") Dr. Dean's employment with Isis terminated 7 years ago and as noted  
10 he does not have a business relationship with Isis. (Dkt. 113-16 ¶ 8.)


11 Santaris has sought throughout the process to grapple with this lack of a  
12 direct relationship by linking Dr. Dean and Isis through Excaliard. These attempts  
13 by Santaris to forge an indirect link are no better founded. Dr. Dean has not been  
14 employed by Excaliard since March 2012, and although he continued to provide  
15 limited consulting assistance to Pfizer related to Pfizer's acquisition of Excaliard,  
16 his consulting work ended by August 2012. (Dkt No. 113-16 ¶¶ 3-4.)


17 Nor did Isis's relationship to Excaliard contain the deep technical and  
18 financial ties that Santaris continues to erroneously suggest. The two companies'  
19 technical relationship has been dead for over 4 years. Excaliard did retain Isis to  
20 perform screening services with respect to potential antisense drug candidates  
21 identified by Excaliard from December 2007 through mid-2008. (Dkt No. 113-16  
22 at ¶ 5.) After mid-2008, those technical services terminated. (*Id.*) Isis's only  
23 technical involvement from that point in time through Excaliard's November 2011  
24 acquisition by Pfizer was a single technical briefing provided to Isis every six  
25 months. (*Id.*) The financial relationship between Isis and Excaliard was that of a  
26 minority equity holder with a small equity interest. (Dkt No. 113-16 at ¶ 6.) Isis's  
27 interest totaled 5% of Excaliard's shares. (*Id.*) Isis had no control over any of  
28 Excaliard's operations. (*Id.*) No Isis representative held a seat on Excaliard's





1 Board of Directors, nor did Isis have any decision-making authority within  
2 Excaliard. (*Id.*)


3 Santaris argues that there is cause for concern founded in Isis's passive right  
4 to receive residual payments from Pfizer relating to Excaliard. (Objection, pp. 8-9.)  
5 Aside from its idle speculation, Santaris offers no real explanation as to how the  
6 right to passively receive residual payments somehow gives rise to an active  
7 confidentiality concern. (*Id.*) Nor is there any. The right to the passive receipt of  
8 payments simply does not equate to the likely transfer of information.


9 With respect to consulting, 


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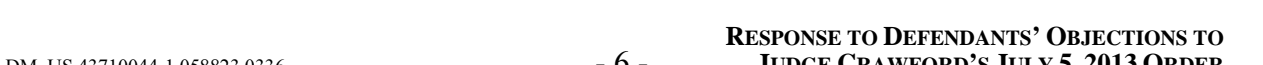
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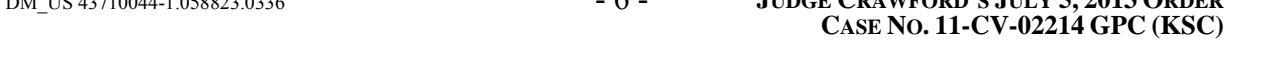
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1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 **2. Robert D. Brown, Ph.D.**

8 Santaris claims that there are numerous available alternative experts.  
9 (Objection, pp. 14-15.) Santaris's own expert designations, however, demonstrate  
10 the contrary. (Dkt. No. 113-1 ¶ 19, Ex. 13.) Santaris has disclosed that it intends to  
11 proffer testimony from Robert D. Brown, Ph.D. ("Dr. Brown"). (Dkt. No. 113-1 ¶  
12 19, Ex. 13.) Dr. Brown touts himself as "one of the only R&D executives in the  
13 biotechnology industry to follow a systemically administered oligonucleotide  
14 therapeutic (Genasense™) from the research bench through Phase 1, 2 and 3  
15 clinical trials and NDA review." (*Id.* at Ex. 14, p. 99.) This experience is  
16 apparently of significant importance to Santaris, who has identified Dr. Brown as  
17 one of only two third party experts from whom it ultimately intends to submit  
18 testimony. (Dkt. No. 149-1, ¶ 16, Ex. 10; Disc. Hr. Tr. at 26:18-22 (Santaris  
19 Counsel Fred Brown at the May 6 hearing: "It's most likely we are only going to  
20 use Dr. Brown and Dr. [Ohlstein].")

21 Santaris intends to rely upon and disclose "Confidential Information" to Dr.  
22 Brown despite the fact that he is a "competitive decision maker." Dr. Brown serves  
23 as the Chief Scientific Officer and head of Research and Development for Dicerna  
24 Pharmaceuticals, Inc. ("Dicerna"). (Dkt. No. 149-1 ¶ 16, Ex. 10.) [REDACTED]

25 \_\_\_\_\_  
26 4 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

"  
"

Apparently unable

itself to locate an unaffiliated third party expert with sufficient experience in antisense drug discovery and development, Santaris has nevertheless elected to disclose to Dr. Brown "Confidential Information," and utilize him as an expert in this case.<sup>5</sup>

As a Dicerna officer, Dr. Brown is in a position to directly influence a core business model that sounds remarkably similar to that of Isis and Santaris: "Strategic alliances are an integral part of Dicerna's corporate strategy. The company is committed to collaborating with partners who have a shared passion for realizing the significant potential of [RNAi] therapeutics for disease areas with high unmet medical need." (Dkt. No. 149-1, ¶ 21, Ex. 14.) That Santaris would choose to work with Dr. Brown is at odds with its litigation concern that even "the identity of the RNA targets that Santaris is pursuing" stands among its most sensitive information.

### C. THE ORDER

In the Order at issue, which is further described below, Judge Crawford noted

<sup>5</sup> Isis has objected to Dr. Brown noting that while it disagrees with the standards Santaris has attempted to impose with respect to Dr. Dean, that until the objections to Dr. Dean are fully resolved "Isis is applying the same standards to Dr. Brown as a matter of fairness and to ensure that the same legal standards are to apply to each party. Once the Court rules on Santaris's position with respect to Dr. Dean, Isis will reevaluate its position with respect to Dr. Dean." (Dkt. No. 175-4, Ex. 17.)

1 that the Protective Order provides that the approval of independent experts shall not  
2 be unreasonably withheld. (Dkt. No. 172, p. 2.) She further noted that the Court is  
3 empowered under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure to  
4 control whether or how certain confidential information is revealed during the  
5 course of discovery. (*Id.*, p. 4.) Both the original Protective Order and the  
6 Amended Protective Order specifically cite this same rule. (Dkt. No. 59, p. 1; Dkt.  
7 No 144, p. 1.)

8 Judge Crawford concluded, among other things, that Dr. Dean does consult  
9 for some Santaris competitors, either directly or indirectly. (Dkt. No. 172, pp. 7-9.)  
10 Judge Crawford went on, however, to make clear that under *Brown Bag* and  
11 *Santella*, “[a] competitive relationship alone...is not sufficient to find that [a  
12 proposed expert] will inadvertently disclose [the producing party’s] confidential  
13 information.” (*Id.* p. 9 (*citing Brown Bag Software v. Symantec Corp.*, 960 F.2d  
14 1465 (9th Cir. 1992) and *Santella v. Grizzly Industries, Inc.*, 2012 U.S. Dist. LEXIS  
15 158349 (D. Or. Nov. 15, 2012)).

16 As part of this inquiry, Judge Crawford made the factual finding that Dr.  
17 Dean nevertheless posed a “relatively minor” or “modest risk” of inadvertent  
18 disclosure. She found that Dr. Dean is “not a traditional ‘competitive decision  
19 maker’,” but “[g]iven Dr. Dean’s status as an active consultant in the field, the  
20 narrow scope of his consulting work, and the nature of the information at issue (the  
21 identities of gene targets, when there are ‘tens of thousands of gene from which to  
22 choose), the Court finds there to be some potential risk of inadvertent disclosure of  
23 defendants’ confidential information.” (*Id.*, p. 11.)

24 Judge Crawford further found, however, that the risk of inadvertent  
25 disclosure was minimal, noting “[g]iven Dr. Dean’s agreement to be bound by the  
26 Amended Protective Order entered in this case, and the patent prosecution bar  
27 included therein, and his assurance that he would discontinue a consultancy if it  
28 triggered a conflict with something derived from defendants’ confidential

1 information in this case, there is a relatively minor risk” that Dr. Dean’s “future  
2 decisions may be made in partial reliance on that information.” (*Id.*, p. 11.) She  
3 also concluded that “the modest risk of inadvertent disclosure of defendants’  
4 confidential information within this admittedly small field does not justify  
5 defendants’ demand that Dr. Dean be precluded from serving as an expert witness  
6 in this case.” (*Id.*)

7 Judge Crawford then assessed the second part of the *Brown Bag* equation,  
8 weighing against the minimal risk the prejudice to Isis from denying Dr. Dean  
9 access. (*Id.* pp. 11-13.) Quoting Judge Moskowitz’s order on Santaris’s first MSJ,  
10 Judge Crawford concluded that “it is essential for plaintiff to have an antisense  
11 expert qualified to testify regarding the process of drug development and  
12 discovery.” (*Id.*, pp. 12-13.) She went on to reach the factual conclusion that  
13 “[w]ith only two products approved by the FDA in the antisense industry’s more  
14 than 20 year history, the pool of experts qualified to testify regarding drug  
15 discovery and development is a small one.” (*Id.*, p. 13.)

16 Judge Crawford then specifically referenced Santaris’s retention of Dr.  
17 Brown, noting that Santaris’s “selection of a senior-management level executive of  
18 a competitor and voluntary disclosure of its own confidential information to him  
19 underscores the limited number of experts in this small field qualified to serve as  
20 expert witnesses.” (*Id.*) Thus, Judge Crawford concluded “[b]ased on the small  
21 size and highly specialized nature of the antisense industry, especially in light of  
22 defendants’ choice of a direct competitor as its own expert, denying Dr. Dean  
23 access to defendants’ confidential information would unreasonably limit and impair  
24 plaintiff’s ability to prosecute its case at trial and defend itself against defendants’  
25 anticipated renewed MSJ.” (*Id.*)

26 Given the high risk of prejudice to Isis and the “relatively minor” or  
27 “modest” risks to Santaris, Judge Crawford ordered that Dr. Dean be granted access  
28 to Santaris “Confidential Information.” (*Id.*, p. 14.)

### 1 **III. ARGUMENT**

#### 2 **A. STANDARD OF REVIEW**

3 A party may file objections to a non-dispositive pretrial order issued by a  
4 magistrate judge within 14 days after being served with a copy of the order. Fed. R.  
5 Civ. P. 72(a). The magistrate judge's disposition may set aside only if it is "clearly  
6 erroneous" or "contrary to law." *Id.*; 28 U.S.C. § 636(b)(1)(A). Factual findings  
7 inherent in discovery disputes are among the non-dispositive pretrial matters that  
8 are reviewed under the "clearly erroneous" standard. *See Grimes v. City and*  
9 *County of San Francisco*, 951 F.2d 236, 240 (9th Cir. 1991) (holding that discovery  
10 sanctions are non-dispositive pretrial matters that are reviewed for clear error under  
11 Rule 72(a)). Legal conclusions are reviewed de novo to determine whether they are  
12 contrary to law. *Central Valley Chrysler-Jeep v. Witherspoon*, 2006 U.S. Dist.  
13 LEXIS 63282, at \*8 (E.D. Cal. 2006).<sup>6</sup>

14 The "clearly erroneous" standard is "significantly deferential, requiring a  
15 "definite and firm conviction that a mistake has been committed.'" *Id.* at \*7.

#### 16 **B. RESPONSE TO OBJECTION 1: SANTARIS MISSTATES THE TERMS OF** 17 **THE PROTECTIVE ORDER**

18 For its first objection, Santaris argues that (1) "each party agreed that there  
19 would be just one limitation on a producing party's right to object to a proposed  
20 disclosure to a particular expert: a party's approval must not be 'unreasonably  
21 withheld'; and (2) the Order "never finds that Santaris's objection to Dr. Dean is  
22 unreasonable, and indeed writes this protection out of the protective order."  
23 (Objection, p. 6).

24  
25 <sup>6</sup> *See also McFarlane v. Life Insurance Company of North America*, 999 F.2d 266,  
26 267 (7th Cir. 1993) (Where the issue presented does not concern "an unadulterated  
27 legal conclusion, but rather the application of a legal standard to a particular set of  
28 facts...the corresponding review is for clear error. Only if the [magistrate] judge  
misapprehends the governing rule of law does our review become more  
searching.").

1 This objection ignores that Judge Crawford specifically cited in her Order the  
2 language in the Protective Orders that approval of experts shall not be unreasonably  
3 withheld. Santaris's criticisms of Judge Crawford also ignore that the parties  
4 extensively briefed and argued the alleged "reasonable" objections Santaris outlines  
5 at pages 8 through 12 of its objections and Judge Crawford addressed those  
6 arguments. For example, her Order expressly addressed Dr. Dean's alleged ties to  
7 Isis both before and after Isis laid him off in 2006 and to Excaliard, as well as the  
8 issue of whether Dr. Dean consults for Santaris's competitors. (Dkt. No. 172, pp.  
9 5-6, 7-9.) In her May 17, 2013 Order, Judge Crawford also addressed Santaris's  
10 complaint that Dr. Dean had not sufficiently disclosed his consulting relationships<sup>7</sup>  
11 and ordered Isis to disclose the names of all companies for which Dr. Dean  
12 currently consults, or has consulted within the last four years, as well as the time  
13 period(s) for each and a brief description of the subject matter of each consultancy.  
14 (Dkt. No. 140, pp. 6-7.) Under these circumstances, any suggestion to the effect  
15 that the Court did not consider Santaris's objections is false.

16 Santaris's objections also ignore that the Protective Orders both contain  
17 express language that the Court could enter an order granting an opposing expert  
18 access to its Confidential Information. In fact, they stipulated to this in the original  
19 Protective Order. Indeed, Santaris cited this language to Judge Crawford multiple  
20 times below before deciding for whatever reason not to cite this portion of  
21 Paragraph 8 of the Protective Order before this Court. (*See* Dkt. 113, at 9, 33.) It

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22 <sup>7</sup> Dr. Dean did not initially disclose the identities of his consulting clients or the  
23 subject matter of such consultancies because he is bound by, and desired to honor,  
24 the terms of his NDAs. (Dkt. No. 113-16 ¶ 14.) After Judge Crawford ordered that  
25 he was to disclose basic information, subject to clear protections for such  
26 disclosure, he complied with that order. Santaris makes much of the fact that  
27 certain of the companies for whom Dr. Dean consults had apparently issued some  
28 public statements acknowledging his retention to provide them with consulting  
services. What that argument misses is that such information is his client's  
information, and it is the client's right to determine what or how much to disclose.  
Dr. Dean simply selected the most conservative path to protect his obligations of  
confidentiality.



1 also ignores that the parties' reference to Rule 26(c)(1)(G) in the Protective Orders  
2 and the Court's citation to this rule in her Order.

3 The original Protective Order, which was in place when Santaris produced  
4 its 1.4 million pages of documents, was not a contract.<sup>8</sup> It was a stipulated  
5 protective order subject to the Court's approval of the order. Nothing in the parties'  
6 stipulated Protective Order stated that the Court could not approve the disclosure of  
7 confidential information over a party's objections, regardless of whether they were  
8 reasonable or not. Nor did the order provide that a party was barred from seeking  
9 Court approval over the other party's objections.

10 Nor did anything in the Protective Order bar the Court from applying Rule  
11 26(c)(1)(G) or *Brown Bag* and its progeny when presented with a request to approve  
12 the disclosure of confidential information to an expert. The same hold true for the  
13 Amended Protective Order. As the *Santella* court recently explained in assessing  
14 whether an expert should be granted access to confidential materials, under the  
15 *Brown Bag* test, the court must balance the risk of disclosure to competitors against  
16 the risk of damaging the claims or defenses of the party seeking access. 2012 U.S.  
17 Dist. LEXIS 158349, at \*4. The court must take into account "factually all the risks  
18 and safeguards surrounding inadvertent disclosure" before granting or denying  
19 access to confidential information. *Id.* Judge Crawford carefully evaluated both  
20 the risk of harm, including all of the risks and safeguards, and extensively analyzed  
21 the risk to Isis of damaging its claims or defenses, thus correctly applying the

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22 <sup>8</sup> Santaris did not assert its reliance cases before Judge Crawford. For example, the  
23 authorities cited in footnote 2 are new, as is the citation to *Beckman Indus., Inc. v.*  
24 *Int'l Ins. Co.*, 966 F.2d 470, 475 (9<sup>th</sup> Cir. 1992) at the bottom of page 7. Moreover,  
25 Santaris's argument in footnote 2 that Judge Crawford erred in stating that it is  
26 Santaris's burden to show "good cause" to extend the Protective Order's protections  
27 is belied by the case law. *Santella*, 2012 U.S. Dist. LEXIS 158349, at \*4 (internal  
28 quotations omitted) (stating, in evaluating request for expert access, "the party  
opposing disclosure has the burden of establishing that there is good cause to  
continue the protection of the discovery material"). Moreover, to the extent that  
Santaris is claiming it relied on the Protective Order, the Protective Orders  
expressly stated that the court could grant approval to one party's expert to review  
the confidential information of another party.

1 *Brown Bag* test.<sup>9</sup>

2 Isis does not dispute that the original Protective Order allowed for the  
3 assertion of objections by the producing party to an “independent expert,”  
4 providing that “[t]he approval of independent experts must not be unreasonably  
5 withheld.” (Dkt. No. 59, ¶ 8.) The original Protective Order articulated no similar  
6 standard with respect to when an expert may be granted access by order of the  
7 Court, instead remaining silent on the subject. (*Id.* ¶¶ 1-28.)

8 In sum, the plain language of Paragraph 8 of the Protective Order, which  
9 Santaris deliberately omitted from its brief, put all parties on notice that the Court  
10 could approve the disclosure of a party’s confidential information. Nothing in the  
11 Protective Order precluded the granting of such approval over a party’s objection,  
12 and that is consistent with Rule 26(c)(1)(G). For these reasons, the Court should  
13 reject Santaris’s first objection.

14 C. **RESPONSE TO OBJECTION 2: JUDGE CRAWFORD HAD THE AUTHORITY**  
15 **TO STRIKE THE DEFINITION OF “INDEPENDENT EXPERT” FROM THE**  
16 **AMENDED PROTECTIVE ORDER**

17 As its second objection, Santaris claims that Judge Crawford erred when she  
18 struck the definition of “Independent Experts” added by Santaris to the Amended  
19 Protective Order. (Objection, pp. 12-13.) At the outset, it should be noted that  
20 Santaris agreed to the original Protective Order, which did not include the definition  
21 of “Independent Expert” which Santaris now argues is indispensable. The revised  
22 order was instead the result of Judge Crawford’s May 17<sup>th</sup> Order that Dr. Dean must  
23 disclose his consulting relationships.

24 Specifically, on October 25, 2012, Judge Crawford entered the original

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25 <sup>9</sup> In the parties’ March 8, 2013 joint motion relating to Dr. Dean, Santaris cited the  
26 Ninth Circuit Court of Appeals’ decision in *Brown Bag* for the proposition that  
27 “[i]n determining whether a protective order limiting disclosure to certain  
28 individuals is warranted, the Ninth Circuit balances the risks that the producing  
party faces from inadvertent disclosure against the risk that the disclosure limitation  
would impair the receiving party’s prosecution of the lawsuit.” (Dkt. No. 113, p.  
40.) Santaris cited extensively to *Brown Bag* and *Santella*.

1 Protective Order (Dkt. No. 59). The original Protective Order was based upon the  
2 then-existing model protective order that had been adopted in this District, and was  
3 entered upon agreed joint motion by the parties. (*See* Dkt. Nos. 58, 59.) As noted,  
4 the Original Protective Order provided that “[t]he right of any independent expert  
5 [to view ‘Confidential Information’] will be subject to the advance approval of such  
6 expert by the producing party *or by order of the Court.*” (Dkt. No. 59 at ¶ 8.)  
7 (emphasis added). The original Protective Order did not set forth a definition of the  
8 phrase “independent expert.” (*See Id.* ¶¶ 1-28.)

9 Under the original Protective Order, “[t]he party seeking approval of an  
10 independent expert must provide the producing party with the name and curriculum  
11 vitae of the proposed independent expert must provide the producing party with the  
12 name and *curriculum vitae* of the proposed independent expert, and an executed  
13 copy of the form attached hereto as Exhibit A...” (Dkt. No. 59, ¶ 8.) These were  
14 the only pieces of information required to be disclosed by the original Protective  
15 Order. (*Id.* ¶¶ 1-28.)

16 On March 8, 2013, the parties filed a joint motion for determination by Judge  
17 Crawford of their dispute with respect to Dr. Dean (Dkt. No. 113) (the “March 8<sup>th</sup>  
18 Motion”). On May 6, 2013, the Court held a hearing on the Joint Motion. (Dkt.  
19 No. 134). The hearing was extensive, involving extensive argument from both Isis  
20 and Santaris. (Dkt. No. 136.) On May 17, 2013, Judge Crawford issued an order  
21 requiring Isis to disclose the names of the companies for which Dr. Dean “currently  
22 consults” and for which he had consulted in the previous four years, as well as the  
23 time periods for each and a brief description of the nature and subject matter of  
24 each consultancy, citing Paragraph 12 of the S.D Cal. Form Protective Order. (Dkt.  
25 No. 140, pp.5-6.) The Court also ordered the parties to jointly submit for the  
26 Court’s signature “an Amended Protective Order, already signed by the parties,  
27 revising the Protective Order already entered in this case...by including Paragraph  
28 12 from the Southern District’s Model Protective Order for patent cases, which is

1 appended to the Southern District’s Local Patent Rules...” (*Id.*, p. 6.) The Court’s  
2 May 17<sup>th</sup> Order did not refer to any other additions or revisions of the then-existing  
3 Protective Order. (*Id.*) It likewise made no reference to the addition of any  
4 definition of the term “Independent Expert.” (*Id.*)

5 On May 21, 2013, Santaris’s counsel forwarded a draft of an Amended  
6 Protective Order. (Declaration of Derek Meyer (“Meyer Decl.”) ¶ 2.) The cover  
7 email from Santaris’s counsel characterized the changes, noting “So you can follow  
8 what we have done: we took the Word version of the previous order as submitted to  
9 the Court, and replaced paragraph 8 with paragraphs 12 and 5 (each slightly  
10 modified) of Court’s standard order. We also slightly modified the definition of  
11 counsel in the order previously submitted to the Court.” (*Id.*) The changes  
12 incorporated the Paragraph 12 as ordered, and also incorporated the definition of  
13 “Independent Expert” from Paragraph 5 of the form order into the revised  
14 Paragraph 8. (*Id.* ¶ 3, Ex. 1.) Isis was not stipulating to this language in the classic  
15 sense of a stipulation but was instead trying to follow the Court’s order to  
16 incorporate Paragraph 12 from the form order, although it learned in the Order that  
17 the parties had misconstrued the scope of the Court’s intent. (*Id.* ¶ 3.)<sup>10</sup>

18 On May 31, 2013, the parties filed a joint motion for entry of the Amended  
19 Protective Order. (Dkt. No. 143.) The Amended Protective Order was entered by  
20 the Court on June 3, 2013. (Dkt. No. 144). Per the May 17<sup>th</sup> Order, the Amended  
21 Protective Order included the language from Paragraph 12 from the Southern  
22 District’s current Model Protective Order governing information to be disclosed by  
23 consultants retained as experts before receiving access to “Confidential  
24 Information.” (*Id.* ¶ 8.) It also included the definition of “Independent Expert” not

25  
26 <sup>10</sup> On May 22, 2013, Isis’s counsel emailed Santaris’ counsel with minor comments  
27 on the proposed amended protective order. The comments included language  
28 indicating that the parties had agreed on the terms of the Protective Order, which  
was true for the original Protective Order, or that the parties had otherwise been  
ordered to be bound by the terms of the Amended Protective Order as set forth in  
Judge Crawford’s May 17, 2013 order. (Meyer Decl., ¶ 4, Ex. 2.)

1 referenced in Judge Crawford's May 17<sup>th</sup> Order. (*Id.*) At the same time, the  
2 Amended Protective Order continued to include the provisions from the Original  
3 Protective Order, prohibiting the parties from making changes to the Protective  
4 Order without leave of Court and expressly permitting Judge Crawford to modify  
5 the Amended Protective Order "in the interests of justice or for public policy  
6 reasons." (Dkt. No. 144 ¶¶ 27, 28.)

7 On June 10, 2013, the parties filed a second joint motion (Dkt. No. 149) (the  
8 "Second Joint Motion"). On July 5, 2013, Judge Crawford issued the Order at  
9 issue. In the Order, Judge Crawford noted that the parties "tacked on onto the  
10 Court-ordered clause was an additional sentence purporting to define the term  
11 'Independent Expert.'" (Dkt. No. 172, p. 4.) She went on to note that "when the  
12 Amended Protective Order was submitted to the Court, the parties failed to disclose  
13 that changes had been made beyond the one amendment specifically ordered." (*Id.*,  
14 p. 4.) She then went on to strike the tacked-on definition, referencing her powers to  
15 modify the Protective Order "in the interests of justice of for public policy reasons."  
16 (*Id.*, p. 4, fn. 2.) She left intact, however, Paragraph 12 of the form's orders  
17 disclosure requirements as required by her May 17<sup>th</sup> Order.

18 Santaris is therefore arguing that the Court had the authority to compel the  
19 parties to amend the Protective Order but lacked the authority to correct the parties'  
20 (or at least Isis's) misunderstanding as to how the order was to be amended as  
21 ordered by Judge Crawford. This argument ignores that the parties originally  
22 stipulated in the original Protective Order and the Amended Protective Order that  
23 the Court could amend its orders. (Dkt. No. 59, p.5:6-8, Dkt. No. 144, p.5:22-24.)  
24 It also ignores the Court's powers under Rule 26(c)(1)(G), as reflected in the Order.

25 Santaris's argument that the definition of "Independent Expert" is necessary  
26 for Paragraph 12 of the Protective Order to properly function is untrue. The  
27 original Protective Order, which was modeled on the then-existing form protective  
28

1 order, contained no such definition.<sup>11</sup> The fact that the first letter of each of the  
2 words is now capitalized does not then somehow render Paragraph 12 unworkable  
3 without the new definition of “Independent Experts” in Paragraph 5 of the form  
4 protective order.

5 Moreover, the application of that definition would, under the facts and  
6 circumstances of this case, be inconsistent with established Ninth Circuit law.  
7 Courts in the Ninth Circuit have repeatedly espoused the *Brown Bag* balancing test  
8 applied by Judge Crawford in determining whether individuals such as Dr. Dean  
9 may appropriately access confidential information. *See, e.g., Santella*, 2012 U.S.  
10 Dist. LEXIS 158349, at \*4. The definition of “Independent Expert” that Santaris  
11 advocates, however, affords no consideration to whether the expert is also a  
12 “competitive decision maker,” the other “risks and safeguards surrounding  
13 inadvertent disclosure,” or the risk of damaging the claims and defenses of the  
14 parties seeking access. *Id.* at \*16 (“A competitive relationship alone, however, is  
15 not sufficient to find that [a proposed expert] will inadvertently disclose [the  
16 producing party’s] confidential information”) (applying *Brown Bag*); *Brown Bag*,  
17 960 F.2d at 1470. Yet, these issues must all be assessed under the Ninth Circuit’s  
18 *Brown Bag* balancing approach. Thus, not only was Judge Crawford’s decision to  
19 strike the definition of “Independent Expert” well within her authority, but it was  
20 also consistent with governing Ninth Circuit law.

21 Santaris’s citation to *Symantec Corp. v. Acronis Corp.*, No. 11-5310 EMC  
22 (JSC), 2012 WL 3582974 (Aug. 20, 2012 N.D. Cal.), on this point is also  
23 misplaced. The court there denied confidential access to a proposed expert who  
24 actively consulted with competitors of the producing party. *Id.* at \*3. The decision,  
25

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26 <sup>11</sup> Moreover, protective orders commonly contain no definition of independent  
27 expert, an issue with which courts have easily grappled by applying a developed  
28 body of case law briefed at length by the parties in their original Joint Motion.  
*Ares-Serono, Inc.*, 153 F.R.D. at 6 (articulating four factor test for determining  
whether expert was independent).

1 did not apply the *Brown Bag* balancing test, but instead applied a far more stringent  
2 standard requiring that the proffered expert “possess unique expertise” before  
3 permitting him confidential access. *Id.*

4 Judge Crawford correctly determined not to follow the nonbinding *Symantec*  
5 decision. First, the facts there limit its reach to “the very specific situation  
6 presented by” its proposed expert, namely, someone who actively consults with true  
7 competitors of the producing party. *Id.* at \*12. Such is not the case with Dr. Dean.  
8 (*See* Section II.B.1, *supra.*) Moreover, the *Symantec* court found that the proffered  
9 expert lacked unique expertise. 2012 WL 3582974 at \*11. Yet, Dr. Dean possesses  
10 uncommon knowledge of an antisense industry with which few individuals have  
11 actual discovery and development experience. (*See* Section II.A, *supra.*)

12 Moreover, *Symantec* was wrongly decided. By its analysis, the very  
13 credentials that qualify someone as an expert in the patented subject matter  
14 (*Symantec*, 2012 WL 3582974 at \*2) become “on-going relationships with  
15 competitors in the field” of the producing party. *Id.* at \*3. Those relationships are  
16 then disqualifying unless the expert has “unique expertise.” If a field has even two  
17 suitable experts, then parties will be *per se* unable to use their chosen expert.  
18 Surely that cannot be the law, and is contrary to *Brown Bag*’s balancing  
19 requirement. Moreover, with all due respect to the *Symantec* Court, the decision  
20 appears unreliable as it states that it could find no case within the Ninth Circuit on  
21 the issue. *Id.* at \*11 n.1. *Symantec* plainly did not consider either *Brown Bag* or  
22 *Santella*.

23 Accordingly, Judge Crawford’s decision to strike the definition of  
24 “Independent Expert” from the Amended Protective Order did not constitute error.

25 **D. RESPONSE TO OBJECTION 3: THE ORDER IS CORRECTLY DECIDED**  
26 **ON THE ISSUE OF PREJUDICE**

27 Santaris argues that Judge Crawford erred because her Order “fram[ed] the  
28 inquiry as whether Isis would be prejudiced if it lacked any antisense expert” and,

1 according to Santaris, Isis should just name a different expert. (Objection, pp.14-  
2 15).

3 Judge Crawford correctly framed the issue, and her factual findings that  
4 “denying Dr. Dean access to defendants’ confidential information will  
5 unreasonably limit and impair plaintiff’s ability to prosecute its case at trial and  
6 defend itself against defendants’ anticipated renewed MSJ on the safe harbor issue”  
7 (Dkt. No. 172, at 13.)<sup>12</sup> were not clearly erroneous.

8 As Isis explained below, Isis and its counsel have engaged, without success,  
9 in extensive efforts to find an expert with comparable expertise to that of Dr. Dean.  
10 (Dkt. No 113-1 ¶ 18.) All of the other experts contacted or considered in that  
11 process: (i) had relationships with Isis or another competitor of Santaris; (ii) lacked  
12 experience as an employee of an antisense drug discovery company; or (iii)  
13 ultimately determined that they were unwilling to serve as an expert in this dispute.  
14 (*Id.*) Although Santaris superficially cites to the numbers returned by various  
15 inquiries as support for its claim that the world is replete with such individuals, it  
16 has never actually identified any expert from those lists who possesses similar  
17 experience in antisense drug discovery and development and does not have a  
18 potentially disqualifying relationship with an Isis competitor.<sup>13</sup>

19  
20 <sup>12</sup> Judge Crawford also correctly recognized the prejudice from Isis in the form of  
21 the substantial time and expense that it has devoted to Dr. Dean, with whom its  
22 counsel worked extensively in connection with Santaris’s first MSJ.

23 <sup>13</sup> A basic review of Santaris’s supposedly probative lists undercuts its claim that  
24 these lists are broadly replete with such experts. For example, Santaris’s assertion  
25 that a search on Westlaw for antisense or oligonucleotide yields over 500 “results”  
26 is highly misleading. (Objection, p. 15.) A high proportion of those results are  
27 simply duplicate references to the same purported experts, with numerous experts  
28 listed multiple times, including many that are listed 10 or more times. Of the actual  
unique experts contained within that list, the overwhelming majority appear to have  
been included by virtue of their publication of just one or two passing articles  
regarding a single experiment or series of experiments utilizing antisense  
oligonucleotides. Many of those articles are extremely dated, and thus do not  
reflect current expertise necessary to evaluate Santaris’s Safe Harbor affirmative  
defense.. The remainder either lacked sufficient practical experience or appear to  
have relationships with “competitors” that would be deemed disqualifying under  
the standards urged by Santaris. (Dkt. No. 149, p. 17.)



1 Judge Crawford was also mindful of Santaris's own conduct, of which she  
2 rightfully took note in her Order. Santaris clearly viewed Dr. Brown's drug  
3 discovery and development experience as important, given that Santaris has  
4 retained him as one of the only two external experts who remained on its list when  
5 Santaris subsequently pared it down. (Disc. Hr. Tr. at 26:18-22.) As the Chief  
6 Scientific Officer of Dicerna, he undoubtedly would qualify as a "competitive  
7 decision maker" under the *Brown Bag* test.

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11  
12 Santaris also ignores Judge Crawford's factual finding that the "pool of  
13 experts qualified to testify to the process of drug discovery and development is a  
14 small one" and that Santaris's choice of Dr. Brown "further bolsters this  
15 conclusion." (Dkt. No. 172, p. 13.) These factual findings are also subject to great  
16 deference by this Court. *See Central Valley*, 2006 U.S. Dist. LEXIS 63282, at \*7.

17 Finally, Santaris trots out again the argument that Isis already has two  
18 experts. (Objection, p. 15.) Santaris made this same argument to this Court on  
19 June 20, 2013 in connection with the parties' dispute over whether the briefing  
20 schedule on the renewed summary judgment motion should be amended because at  
21 the time the issues relating to Dr. Dean had not been ruled on by Judge Crawford.  
22 (Dkt. 168, p. 4.) As Isis has explained, in addition to Dr. Dean, Isis's attorneys  
23 have also retained two other experts, Elizabeth Gordon, Ph.D., and Claire Gelfman,  
24 Ph.D. (Dkt. No. 113-1 ¶ 2.) Both experts fill different roles than Dr. Dean. Dr.  
25 Gordon is a former FDA official who regularly consults on regulatory issues. (Dkt.  
26 No. 113-18 ¶¶ 2, 12-16.) Dr. Gordon has been retained to provide opinions and  
27 information regarding the process by which FDA considers investigational new  
28 drugs, and in particular, the scope and content of information submitted to FDA by

1 drug sponsors in an Investigational New Drug Application. (Dkt. No. 113-1 ¶ 2.)  
2 Dr. Gelfman has been retained by Isis’s counsel as a technical consultant to assist in  
3 interpreting the large volume of scientific documents produced by Santaris in this  
4 matter. (*Id.* ¶ 4.) As Dr. Gelfman’s curriculum vitae disclosed, she has a Ph.D. in  
5 Molecular Biology, but does not have experience in the antisense drug discovery  
6 issues that are the subject of Dr. Dean’s anticipated opinions. (*Id.* ¶ 5, Ex. 3, pp.  
7 25-28.)

8 This Court rejected Santaris’s argument that Isis already has two experts on  
9 June 20, 2013, and specifically found that Isis would be prejudiced by having to  
10 brief Santaris’s renewed motion for summary judgment “without the benefit of it’s  
11 expert’s contributions in less time than originally provided by this Court’s briefing  
12 schedule.” (Dkt. No. 170, p. 3.) For all of these reasons, Santaris’s third objection  
13 to the Order should be rejected.

14 **E. RESPONSE TO OBJECTION 4: JUDGE CRAWFORD’S FINDING OF “A**  
15 **MODEST RISK OF INADVERTENT DISCLOSURE” WAS NOT CLEARLY**  
16 **ERRONEOUS**

17 For its fourth objection, Santaris asserts that Judge Crawford erred because  
18 she erroneously relied upon Dr. Dean’s “assurances that he would discontinue a  
19 consultancy if it triggered a conflict with something derived from defendants’  
20 confidential information” when making its factual finding that the “relatively minor  
21 risk” or “modest risk of inadvertent disclosure of defendants’ confidential  
22 information within this admittedly small field does not justify defendant’s demand  
23 that Dr. Dean be precluded from serving as an expert in this field.” (Objection, pp.  
24 15-16.)

25 Again, Santaris has not presented the full picture to the Court. Judge  
26 Crawford listed two other factors before this factor in her Order. (Dkt. No. 172, p.  
27 13.) She first cited Dr. Dean’s agreement to be bound by the terms of the  
28 Protective Order, and the patent prosecution bar cited therein, when making this  
finding. (*Id.*) These terms protect Santaris. Specifically, the Amended Protective

1 Order contains a patent prosecution bar, extending for a period of five years after  
2 the resolution of this matter, including any and all appeals. (Dkt. No. 144, ¶ 12.)  
3 By signing Exhibit A to the Protective Order, Dr. Dean also agreed under penalty of  
4 perjury to be bound by and comply with the Protective Order's terms. (*Id.*, pp. 15-  
5 16, ¶¶ 2, 3.)

6 As for the third factor she cited, Dr. Dean has agreed: "in the unlikely event  
7 that I come across a non-disclosed Santaris target that my other client is working on  
8 I will ceased reviewing the document and will refrain from any further consulting  
9 on that specific target. Because I will not have reviewed the information and will  
10 not review other documents on the target, the information would be of little value. I  
11 reiterate that in my 30 years of researching and working in the antisense field, I  
12 have never had an issue with maintaining one client's confidences when working  
13 for another client despite having far great access to information than I would have  
14 here where I would cease work on a target before I learned any details." (Dkt. No.  
15 113-17, ¶ 5.) This is not materially different, particularly under the applicable  
16 "clearly erroneous" from how Judge Crawford characterized this agreement in her  
17 Order. Santaris's "odd carve-out" objection on this point assumes without basis  
18 that Dr. Dean would need to disclose the basis of his termination of work as  
19 opposed to simply ceasing his consultancy on the subject target without sharing any  
20 details relating to Santaris. Santaris's fourth objection should therefore be rejected.

#### 21 **IV. CONCLUSION**

22 For the foregoing reasons, Isis respectfully requests that the Court  
23 affirm Judge Crawford's Order. Santaris cannot show that the Court's factual  
24 findings were clearly erroneous and if this Court were to somehow determine that  
25 Santaris's objections address pure legal issues, Santaris has failed to identify any  
26 portion of the order that is contrary to law. Moreover, Isis has been prejudiced by  
27 the prolonged delays relating to Dr. Dean's ability to review Santaris's confidential  
28 information in both the depositions that have already occurred in this case, as well

1 as in connection with Isis's preparations for Santaris's second motion for summary  
2 judgment.

3 Dated: July 16, 2013

McDERMOTT WILL & EMERY LLP

4  
5 By: /s/ William G. Gaede, III  
6 William G. Gaede, III

7 Attorneys for *Isis Pharmaceuticals, Inc.*  
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